

### **REMARKS**

Claims 1, 2, 5, 6, 7, 8, 13, 15 and 16 have been amended. No new matter has been added. Support for the claim amendments may be found throughout the specification. Claims 3-4 and 17-45 have been cancelled without prejudice. Applicants reserve the right to prosecute the subject-matter of those claims in a continuing application.

The Examiner has deemed the restriction requirement to be proper and made final.

Claims 1, 2 and 5-16 are pending.

### **INFORMATION DISCLOSURE STATEMENT**

The Examiner states that "the listing of references in the specification is not a proper information disclosure statement." See Office Action at p. 3. A Supplemental Information Disclosure Statement and Form 1449 was filed on January 7, 2009. The Supplemental IDS and Form 1449 cited among other references: Stem. Cells: Scientific Progress and Future Research Directions The National Institute of Health (2001); Braeckmans, Kevin, et al., "Scanning the code encoded microcarrier beads signal the way to better combinatorial libraries and biological assays," Modern Drug Discovery (2003) pgs. 28-32; Johe, K. K., et al., "Single factors direct the differentiation of stem cells from the fetal and adult nervous system," Genes Dev. (1996) Vol. 10 pgs. 3129-3140; Wagner, Joseph, et al., "Induction of a midbrain dopaminergic phenotype in Nurr1- overexpressing neural stem cells by type 1 astrocytes," Nature Biotechnology (1999) Vol. 17 pgs. 653-659. Applicants respectfully request the consideration of these references and others submitted with the Form 1449 and Supplemental IDS on January 7, 2009.

### **SPECIFICATION**

The Examiner has objected to the disclosure as "it contains an embedded hyperlink and/or other form of browser-executable code ...." See Office Action at p. 4. Applicants have amended the relevant paragraphs on p. 1 and 19 of the specification and removed the embedded hyperlinks. Applicants respectfully request the withdrawal of this objection.

### **CLAIM OBJECTION**

The Examiner has objected to claim 4 as "[c]laim 4 does not further limit claim 2 because it is essentially a duplicate of claim 2." See Office Action at p. 4. Applicants have cancelled claim 4 and respectfully request the withdrawal of this objection.

### **CLAIM REJECTION**

#### ***Rejection of claims under 35 U.S.C. 102(b)***

The Examiner has rejected claims 1, 2, 4-8, 10 and 12-16 under 35 U.S.C. § 102(b) as being anticipated by Nishikawa et al. (*Development*, 1998; Vol. 125, p. 1747-1757) (“Nishikawa”). See Office Action at p. 5. Claim 4 has been cancelled thus rendering this rejection moot with respect to claim 4. Claims 10 and 12-16 depend from independent claim 1 and 2.

Claim 1 relates to a method for determining the effect of a plurality of culture conditions on a cell, including the steps of: (a) providing a first set of groups of cell units each including one or more cells, and exposing the groups to desired culture conditions, (b) subdividing one or more of the groups to create a further set of groups of cell units, (c) exposing the further groups to further desired culture conditions, (d) repeating steps (b)-(c) iteratively as required and (e) assessing the effect on a given cell unit of the culture conditions to which it has been exposed.

Claim 2 relates to a method for determining the effect of a plurality of culture conditions on a cell, including the steps of a) providing a first set of groups of cell units each including one or more cells, and exposing the groups to desired culture conditions, (b) pooling two or more of the groups to form at least one second pool, (c) subdividing the second pool to create a further set of groups of cell units, (d) exposing said further groups to desired culture conditions, (e) repeating steps (b)-(d) iteratively as required and (f) assessing the effect on a given cell unit of the culture conditions to which it has been exposed.

Nishikawa describes that “CCE ES cells ... were initially maintained in Mitomycin C ... treated embryonic fibroblast layers in Dulbecco modified essential medium (DMEM: Gibco) ...” See p. 1748. Nishikawa further describes transferring ES cells “to gelatin (Sigma, USA)-coated culture dishes to remove fibroblasts.” *Id.* Nishikawa also states that “ $10^4$  ES cells were then transferred to each well of type IV collagen-coated 6-well cluster dishes ... and incubated in a-MEM supplemented with 10% FCS and  $5 \times 10^{-5}$  M 2ME.” *Id.* Nishikawa then describes harvesting the cells. *Id.*

Nishikawa does not describe a method for determining the effect of a plurality of culture conditions on a cell that includes the steps of: (a) providing a first set of groups of cell units each including one or more cells, and exposing the groups to desired culture conditions, (b) subdividing one or more of the groups to create a further set of groups of cell units, (c) exposing

the further groups to further desired culture conditions, (d) repeating steps (b)-(c) iteratively as required and (e) assessing the effect on a given cell unit of the culture conditions to which it has been exposed. Nishikawa also does not describe a method for determining the effect of a plurality of culture conditions on a cell, that includes the steps of a) providing a first set of groups of cell units each including one or more cells, and exposing the groups to desired culture conditions, (b) pooling two or more of the groups to form at least one second pool, (c) subdividing the second pool to create a further set of groups of cell units, (d) exposing said further groups to desired culture conditions, (e) repeating steps (b)-(d) iteratively as required and (f) assessing the effect on a given cell unit of the culture conditions to which it has been exposed.

Since Nishikawa does not describe that the split-split or pool-split steps are repeated as described in claims 1 and 2, dependent claim 10 and 12-16 should be patentable over Nishikawa for at least the same reasons described above. Applicants respectfully request reconsideration and the withdrawal of this rejection.

***Rejection of claims under 35 U.S.C. 102(e)***

The Examiner has rejected claims 1, 2 and 4-16 under 35 U.S.C. § 102(e) as being anticipated by U.S. Publication No. 2004/0170965 to Scholl et al. ("Scholl"). See Office Action at p. 6. Claim 4 has been cancelled thus rendering this rejection moot with respect to claim 4. Claims 10 and 12-16 depend from independent claim 1 and 2.

Scholl describes that [c]ells to be cultured were harvested by first rinsing source cell monolayers with Hank's Balanced Salt Solution (HBSS) without magnesium or calcium." See paragraph [149] of Scholl. Scholl further describes that "[d]epending upon the cell line, the cells were dissociated by adding trypsin ... or trypsin-EDTA" and adding cell culture medium to the trypsinized cell suspension. *Id.* Scholl also describes diluting the trypsinized cell suspension "to produce an optical density of cell suspension suitable to produce a confluent monolayer of cells within 2-3 days of incubation in a 96-well microtiter plate." *Id.*

Scholl does not describe a method for determining the effect of a plurality of culture conditions on a cell that includes the steps of: (a) providing a first set of groups of cell units each including one or more cells, and exposing the groups to desired culture conditions, (b) subdividing one or more of the groups to create a further set of groups of cell units, (c) exposing the further groups to further desired culture conditions, (d) repeating steps (b)-(c) iteratively as required and (e) assessing the effect on a given cell unit of the culture conditions to which it has

been exposed. Scholl also does not describe a method for determining the effect of a plurality of culture conditions on a cell, that includes the steps of a) providing a first set of groups of cell units each including one or more cells, and exposing the groups to desired culture conditions, (b) pooling two or more of the groups to form at least one second pool, (c) subdividing the second pool to create a further set of groups of cell units, (d) exposing said further groups to desired culture conditions, (e) repeating steps (b)-(d) iteratively as required and (f) assessing the effect on a given cell unit of the culture conditions to which it has been exposed.

Since Scholl does not describe that the split-split or pool-split steps are repeated as described in claims 1 and 2, dependent claim 10 and 12-16 should be patentable over Scholl for at least the same reasons described above. Applicants respectfully request reconsideration and the withdrawal of this rejection.

### **CONCLUSION**

Applicant believes that the claims are in condition for allowance. A petition for a two-month extension of time is attached.

Should any fees be required by the present Reply, the Commissioner is hereby authorized to charge Deposit Account 19-4293.

Respectfully submitted,

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